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August 13, 1993

Dockets Management Branch (HFA-305)  
Food and Drug Administration, Rm 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Subject: Docket 93N-0044, Intent to Amend Laser Performance

Dear Sir/Madam:

The suggested amendments to the laser performance standard FDA 21 CFR Part 1040 is a welcomed change and I hope that the changes are implemented soon.

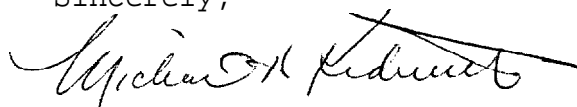
I do have a concern about item 2 in the amendments under consideration. Paragraph 2 excludes surveying lasers from the 100 second maximum exposure limit. It is not clear to me why these products have been excluded since viewing the laser on these products is not intended and the design of the products intends that the beam be viewed by electronic or mechanical devices. If there were surveying products which the beam is to be intentionally viewed, they would not be in compliance with current OSHA regulations.

I strongly believe that the Food and Drug Administration should revise this amendment under consideration. If item 4 under consideration is adopted without revising item 2 to include surveying instruments in the 100 second exposure time, the requirements for surveying lasers **will** become more restrictive for the products that we sell in the U.S. This conflicts with the accident-free record that surveying instruments have had in the United States over the last 25 years.

With the exception of the above item, I am in general agreement with all of the changes and again believe that surveying instruments should be included in item 2.

Thank you for your attention to this matter.

Sincerely,



**Michael H. Kidwell**  
Quality Assurance Manager

MHK/rm

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**Spectra-Physics**

**LASERPLANE**

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